DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 28, 2014

Shenzen Jumper Medical Equipment Co., Ltd.
C/O Field Fu, Consultant
Shenzen Joyantech Consulting Co., Ltd
4th Floor, Jinhui Building
Nanhai Blvd. Nanshan District, Shenzen
Guangdong, China 518000

Re: K140582
Trade/Device Name: JPD-500A Fingertip Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: July 21, 2014
Received: July 31, 2014

Dear Mr. Fu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Chapter 04 Indications for Use

510(k) Number (if known): K140582

Device Name: Fingertip Pulse Oximeter
Model: JPD-500A

Indications for Use:

The JPD-500A Fingertip Pulse Oximeter is non-invasive device intended for spot-checking of functional oxygen saturation of arterial hemoglobin (Spo2) and pulse rate. The portable fingertip device is indicated for adult and pediatric patients in home and hospital environments (including clinical use in internist/ surgery, anesthesia, intensive care, etc).

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sponsor: *Shenzhen Jumper Medical Equipment Co., Ltd.*
Subject Device: *Fingertip Pulse Oximeter, model: JPD-500A*

Chapter 05 510(k) Summary

510(K) Summary as required by 21 CFR 807.92(c).

1.0 Information of Submitter and Correspondent

Submitter's information:

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Contact person: Mr. Field.Fu E-mail: cefda13485@163.com

2.0 Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Fingertip Pulse Oximeter
Model:	JPD-500A
Classification name:	Oximeter
Review Panel:	Anesthesiology
Product Code:	DQA
Device Class:	II
Regulation Number:	870.2700

3.0 Predicate Device Information

Sponsor:	Contec Medical Systems Co., Ltd.
Device:	CMS-50D Finger Pulse Oximeter
510(K) Number:	K082641

Sponsor: *Shenzhen Jumper Medical Equipment Co., Ltd.*
Subject Device: *Fingertip Pulse Oximeter, model: JPD-500A*

4.0 Device Description

The JPD-500A fingertip pulse oximeter is intended for spot-checking of functional pulse oxygen saturation (SpO2) and pulse rage (PR) of single adult and pediatric patient in home and hospital.

The fingertip pulse oximeter features small size, low power consumption, convenient operation and portability. Power consumption of the product is low and two AAA batteries can be operated continuously for 24 hours. It is only necessary for a patient to put one of his/her fingers into the fingertip clips for measurement, very easy to use it.

Principle of the fingertip pulse oximeter as follows:

A mathematical formula is established making use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin (RHb) and Oxyhemoglobin (HbO2) in glow and near-infrared zones.

Operation principle of the instrument:

Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm glow and 905nm near infrared light) can be focused onto a human nail tip through a clamping finger-type sensor. Relevant data is shown on the Oximeter's display through electronic circuits and a microprocessor.

5.0 Intended Use

The JPD-500A Fingertip Pulse Oximeter is intended for measuring the functional oxygen saturation and pulse rate through patient's finger. It is applicable for spot-checking SPO2 and pulse rate of adult and pediatric patients in homes and clinics.

6.0 Indications for Use

The JPD-500A Fingertip Pulse Oximeter is non-invasive device intended for spot-checking of functional oxygen saturation of arterial hemoglobin (Spo2) and pulse rate. The portable fingertip device is indicated for adult and pediatric patients in home and hospital environments (including clinical use in internist/ surgery, anesthesia, intensive care, etc).

7.0 Summary comparing technological characteristics with predicate device

Sponsor: *Shenzhen Jumper Medical Equipment Co., Ltd.*
Subject Device: *Fingertip Pulse Oximeter, model: JPD-500A*

Technological Characteristics	**Comparison result**
Design principle	Same
Appearance	Similar
Patients contact materials	Same
Performance	Similar
Biocompatibility	Same
Mechanical safety	Same
Energy source	Same
Electrical safety	Same
Standards met	Same
EMC	Same
Function	Similar

8.0 Performance Summary

JPD-500A Fingertip Pulse Oximeter conforms to the following standards:

- IEC 60601-1, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, 2005, CORR.1:2006 + CORR.2：2007;
- IEC 60601-1-2:2007 Medical electrical equipment – Part 1-2: General requirements for safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests;
- IEC 60601-1-11:2010 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment;
- ISO 80601-2-61:2011 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter;
- IEC 62304:2006 Medical device software – Software life cycle processes;
- ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process;
- ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for In Vitro cytotoxicity;
- ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.

9.0 Clinical testing

Clinical hypoxia accuracy testing (controlled desaturation study) was conducted during induced hypoxia studies on 10 healthy, nonsmoking, light-to-dlark-skinned subjects in an independent research laboratory. The measured arterial hemoglobin saturation value (SpO2) of the proposed device was compared with arterial hemoglobin oxygen (SaO2) value, determined from blood samples with a CO-oximeter. The accuracy of the device is in comparison with the CO-oximeter samples measured over the SpO2 range of 70-100%. Accuracy data was calculated using the root-mean-squared (Arms value) for all subjects, per ISO 80601-2-61, the result showed that the error is far less than the scope specified in the STANDARD ; and the Agreement between Methods of Measurement with Multiple Observations per each subject was analyzed with the Bland and Altman statistics, the analysis demonstrated that the vast majority of data is within ±95% limit of agreement, the data points beyond or below this scope were regarded as outliers. By analyzing, these few outliers are occasional, which does not raise safety and performance concerns regarding the accuracy of the device.

15 subjects were enrolled for the clinical study, who are healthy, non-smoking, competent adults, between twenty-seven and forty-four (27-44) years of age, they were provided EC (Ethics Committee)-approved informed consent as documented on an informed consent form. 5 patients were excluded during test based on the exclusion criteria and the criteria for determining stability of the SaO2 at the pulse oximeter probe site.

In addition, there were no reported adverse effects during these investigations.

10.0 Comparison to predicate device and conclusion

The subject device JPD-500A Fingertip Pulse Oximeter is substantially equivalent to CMS-50D Fingertip Pulse Oximeter whose 510(k) number is K082641.

Characteristics	Subject device JPD-500A	Predicate device (K082641)	Judgment
Device name	Fingertip Pulse Oximeter	Fingertip Pulse Oximeter	Same
Model	JPD-500A	CMS-50D	--
K Number	Pending	K082641	--

Sponsor: *Shenzhen Jumper Medical Equipment Co., Ltd.*
Subject Device: *Fingertip Pulse Oximeter, model: JPD-500A*

Characteristics	Subject device JPD-500A	Predicate device (K082641)	Judgment
Manufacturer	Shenzhen Jumper Medical Equipment Co., Ltd.	Contec Medical Systems Co., Ltd.	--
Intended patient population	Adult		Same
Intended application site	Fingertip		Same
Intended use	The JPD-500A Fingertip Pulse Oximeter is intended for measuring the functional oxygen saturation and pulse rate through patient's finger. It is applicable for spot-checking SPO2 and pulse rate of audit and pediatric patients in homes and clinics.	This Fingertip Oximeter is intended for measuring the pulse rate and functional oxygen saturation (SpO2) through patient's finger. It is applicable for spot-checking SpO2 and pulse rate of adult and pediatric patients in homes and clinics.	Same
Design principle	A mathematical formula is established making use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin(RHb) and Oxyhemoglobin (HbO2) in glow and near-infrared zones. Operation principle of the instrument: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lightscan be focused onto a human nail tip through a clamping finger-type sensor. A measured signal obtained by a photosensitive element, will be shown on the Oximeter's display through process in electronic circuits and microprocessor.		Same
Prescription or OTC	Prescription		Same
Contact material	Silica gel		Same

Sponsor: *Shenzhen Jumper Medical Equipment Co., Ltd.*
Subject Device: *Fingertip Pulse Oximeter, model: JPD-500A*

Characteristics	Subject device JPD-500A	Predicate device (K082641)	Judgment
SpO2 measuring range	0-100%	35%-99%	Similar
SpO2 accuracy	70%-100%: ±2% 0%-69%: no definition	70%-100%: ±2% 35%-69%: no definition	Similar
Pulse rate measuring range	25-250bpm	30-240bpm	Similar
Pulse rate accuracy	±2bpm	±2bpm or±2% (whichever is greater)	Similar
Operation temperature	5℃-40℃	5℃-40℃	Same
Operation humidity	15%-80%	30-80%RH	Similar
Power source	2 × AAA batteries	Same	
Other function	Low battery voltage alarm; Automatically power off; Alarm limits setting function		Same

11.0 Conclusions

As a comparison result for Clause 7.0, JPD-500A is same as its predicate device in the intended use, the design principle, the material, the performance and the applicable standards. Only their appearance, the SpO2 measuring range and pulse rate range are a little bit different.

However, the test in this submission provides demonstration that these small differences do not raise any new questions of safety and effectiveness to the new device. The proposed device is Substantially Equivalent (SE) to the predicate device which is legally marketed in US. Therefore, the subject device is determined as safe and effective as predicate device.

12.0 Summary prepared date

August 28, 2014